35. The method of claim 34, wherein said solid constituent comprises a capsule.

36. The method of claim 34, further comprising removing said first lid from said sealed relationship with said second lid and thereby exposing said syringe-receiving stopper and maintaining said sterile environment.

37. The method of claim 36, wherein said third lid is removed by peeling said third lid from said second lid.

38. The method of claim 36, further comprising inserting a syringe into the container through said syringe-receiving stopper and withdrawing said combined constituents.

39. The method of claim 34, wherein said combined constituents comprise a medicinal preparation.

## REMARKS

It is noted that the drawings were objected to under 37 CFR 1.83(a) because the plural constituents recited in claim 28 were not shown in the drawings. Inasmuch as claim 28 is now cancelled and plural constituents are not recited in any of the newly submitted claims, it is believed that the drawing objection is satisfied.

Claims 1-6, 9-11, 13-19, and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (U.S. 2,275,567) in view of Barasch, et al. (U.S. 2,764,983). The Examiner considered that the Smith device was implicitly meant to be used with a syringe and in a sterile environment and further that Barasch et al. teaches the use of a well and a self-sealing stopper.

Claims 1, 2, 8-11, 13, 14, 19, 20, and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nosik (U.S. 2,721,552) in view of Crankshaw (U.S. 4,084,432). The Examiner considered that Nosik disclosed a multi-chamber having two sterile seals, an introducer, and a syringe-receiving portion but not a removable cover. The addition of a

protective cover to the device of Nosik was stated to be obvious in view of Crankshaw's protective cover. The position of stopper (13) of Nosik was deemed to serve as an indicator.

Claims 1-5, 8-17, 19, 20, and 29 stand rejected under 35 U.S.C. 103(a) as unpatentable over Smith (U.S. 2,652,611) in view of Crankshaw (U.S. 4,084,432). Smith was deemed to show the claimed features but not a protective cover. Crankshaw was applied for the purpose of rendering the addition of a protective cover to the Smith container to be obvious.

Claims 6 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nosik in view of Crankshaw as applied to claim 1 taken further in view of Ravinski (U.S. 3,779,371). The Examiner deemed that Rovinski's test tube having a tapered bottom forms a well and that such additional feature would be an obvious addition.

Finally, Claim 28 was rejected under 35 U.S.C. 103(a) as unpatentable over Nosik in view of Crankshaw et al. or Smith in view of Barasch et al. as applied to claim 1 taken further in view of Baumann et al. (U.S. 3,762,540). The Examiner concluded that the use of Baumann's three material chambers would constitute an obvious addition..

It is respectfully believed that the above-mentioned rejections under 35 U.S.C. 103(a) are not applicable to the newly presented claims and thus should not be repeated because none of the references applied in the above stated rejections under 35 U.S.C. 103(a) disclose or suggest the highly advantageous combination of features set forth in new claims 30-39. The claimed constituent delivery system is characterized by a highly efficient mode of operation and desirable preservation of sterility during such operation.

The claims provide that the system employs a three-part lid to seal and initially preserve the sterility of both the solid and liquid constituents that are later to be combined. Sterility of constituents is preserved throughout the combination and dispensing procedures, thus avoiding the need for subsequent sterility procedures. Obviously, such dispensing method is highly advantageous and necessary should the device be used in an environment where subsequent sterilization is difficult or impossible.

The three lids have a cooperative function, and thus all three lids must be present and have specific properties and structure for the system of the invention to operate in its advantageous mode. During operation of the system, sufficient pressure is applied to a portion of the top lid and transmitted through the middle lid to the solid constituent to cause the solid

constituent, which is sterilely contained between the middle and bottom lids, to press against and break the lower lid. Upon such breakage, the solid constituent enters the liquid-containing container where the solid and liquid constituents are combined. Sterility of both constituents, as well as the middle and bottom lids, is preserved because such procedure is conducted while all three lids remain in sealed relationship. Sterility is maintained throughout the dispensing procedure because removal of the top lid exposes the second lid, which remains sterile because its sterility was protected by the top lid during penetration of the solid constituent into the container holding the liquid constituent. Insertion of a syringe into the syringe-receiving stopper located in the middle lid enables the user to withdraw a desired amount of sterile combined product at one time or during selected intervals.

As may be observed from the above explanation, the top lid functions to preserve sterility of the middle lid and its syringe-receiving stopper portion prior to and after the solid constituent breaks through the lower lid and enters into the container to be combined with the liquid constituent. At this point, the combined solid and liquid constituents in the container are preserved as sterile by the middle and top lids following breakage of the lower lid. Sterility is also maintained by the middle lid when the top lid is removed in preparation for dispensing. Accordingly, the middle lid must contain the syringe-receiving stopper for the dispenser and method to function as described above; and the lower lid must be sufficiently weak to permit breakage when pressure is applied to the solid constituent.

It is apparent that none of the prior art cited and applied by the Examiner anticipates the newly claimed invention. This conclusion is underscored by the fact that no novelty rejections were made the Examiner. Applicant respectfully believes that the claimed invention would not be obvious to one of ordinary skill in the art because none of the prior art cited and applied by the Examiner appreciates Applicant's inventive concept and unique combination of steps that results in sterility being preserved at all times during practice of the constituent delivery system invention.

In view of the presentation of new claims 30-39 and the accompanying remarks, Applicant respectfully believes that the instant application is in condition for allowance; and a notice to such effect is respectfully requested.

Should the Examiner have any questions or require additional information or discussion to place the application in condition for allowance, a phone call to the undersigned attorney would be appreciated.

Respectfully submitted,

Date: November 4, 2003

Gerald K. White
Reg. No. 26,611
Attorney for Applicant

**GERALD K. WHITE & ASSOCIATES, P.C.**
**205 W. Randolph Street, Suite 835**
**Chicago, IL 60606**
**Phone: (312) 920-0588**
**Fax: (312) 920-0580**
**Email: gkwpatlaw@aol.com**